UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS NOTICE

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CONTENTS OF NONCOMPLIANCE RECORDS

This notice provides clarification to Food Safety and Inspection Service (FSIS) inspection program personnel regarding standardized language or "tag lines" used on FSIS Form 5400-4, Noncompliance Record (NR). FSIS is issuing this notice in response to questions that have been raised through supervisory channels and in Food Safety Regulatory Essentials (FSRE) training classes.

Inspection program personnel are not to use standard phrases that attempt to characterize the public health context of the noncompliance. Examples include "Continued noncompliance could lead to foodborne illness" or "Continued noncompliance could result in illness or death."

The Consumer Safety Inspector Performance Standard for "Communication" states, "Document noncompliance and regulatory control actions to describe the conditions and circumstances relating to the noncompliance, the significance of the noncompliance from sanitation or public health perspective, and the relationship to the applicable regulatory requirements. Required forms and formats are used, and required documentation is produced." This performance standard reflects the fact that, for NRs to be effective, they need to describe the specific noncompliance. Routine repetition of standardized language is not an acceptable substitute for a description of the conditions and circumstances that are inconsistent with the statutes and regulations that FSIS enforces. If the circumstances are described appropriately, any public health concerns will be apparent.

On NRs, inspection program personnel are to cite the specific regulations with which the establishment has failed to comply (all regulatory citations need to be listed in Block 6 and chosen from the available pull-down menu) and provide a description of the event that constitutes the noncompliance (Block 10) (See Attachment 1 to this Notice). As provided for in FSIS Directive 5000.1, "Verifying an Establishment's Food Safety System," and the FSRE training, inspection program personnel should reference, as appropriate, that continued failure to meet regulatory requirements can lead to

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enforcement actions as described in 9 CFR Part 500.4. This reference is the only additional statement, beyond the complete and accurate description of the circumstances involving a regulatory noncompliance that should be included in block 10 of the NR.

Refer questions to the Technical Service Center at 1-800-233-3935.

Assistant Administrator

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Office of Policy, Program, and Employee Development

Attachment 1

Information inspection program personnel are to include in Block 10 of a noncompliance record:

- A description of each noncompliance in clear, concise terms, including the exact problem, time of occurrence, location, and effect on the product, if any.
- An explanation of how they notified establishment management of the noncompliance.
- When there is a developing trend of noncompliance, a list of previous NRs and a description of how the NRs derived from the same cause. Also, inspection program personnel are to describe any unsuccessful further planned actions taken by the establishment to the noncompliances. Additionally, inspection program personnel are to indicate whether they have discussed the developing trend of noncompliance with establishment management.
- Any applicable deadlines.
- Whether a regulatory control action (tag) was taken.

Examples of information to be included in Block 10:

- At approximately 0410 hours, after the establishment's pre-operational inspection and before the start of production, I performed procedure 01B02. I observed the following noncompliances: Rust on the auger and auger throat of the #2 grinder; rust on the auger and blender arms of the small Hobart grinder; rust on the crossbar on top of the hopper to the stuffer; and dried residue on the blade guides and the bottom of the pulley on both band saws. I applied U.S. "Reject" tags # B 1469277, B 1469278, B 1469279, B 1469280, and B 1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws, respectively. I informed the foreman who immediately had the equipment appropriately cleaned to restore sanitary conditions. Preventive measures: increasing the amount of time spent conducting pre-op monitoring and giving instructions to the cleaning crew to be more observant. A similar noncompliance was documented on NR 27-02, dated May 13, 2002. The preventive measures of modifying the Sanitation SOPs to include a procedure for cleaning the saw blades in a manner that will prevent rust formation and a procedure for soaking the cuber in an acid solution were not implemented or were ineffective in preventing recurrence. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action.
- At approximately 1425 hours, I observed condensation dripping from pipes in the ceiling onto chicken parts on belt #1 in the processing boning room. Belt #1 was U.S. "Rejected" with tag #578688. Approximately 30# of product was U.S. "Retained" with tag #578689. Ms. Jane Doe was notified of the direct contamination of product and the insanitary condition of belt #1. She was

informed that the regulatory control actions would remain in effect until the establishment meets the requirements of 9 CFR 416.15 and 416.2.

At approximately 0940 hours, I observed the QA technician taking the temperature of 5 chicken filets exiting the oven on line #1 for CCP 2. After taking the temperature of the 5 chicken filets, I observed the QA technician record the temperatures in the establishment's HACCP records. The QA technician then left the processing area. I reviewed the HACCP records for that CCP for that day and found that only 5 filets per each hourly check were recorded for that shift starting at 0530. The establishment's monitoring procedures and frequency for CCP 2 require the QA technician or designee to record the temperature of 10 chicken filets exiting the oven on line #1 every hour. The temperature of the product recorded for that day has met the critical limit of ≥ 160°F. I retained the product with U.S. "Retained" tag #687423 and rejected the belt and oven with U.S. "Rejected" tag #687424. Ms. Jane Doe was notified of the noncompliance. She was informed that the regulatory control actions would remain in effect until the establishment demonstrated product safety.